

REMARKS

Claims 1-29 are currently pending in the application. Applicants respectfully request reconsideration of the claims currently pending in the application.

Applicants thank the Examiner for favorable consideration and allowance of claim 29.

1. Rejections under 35 USC § 102

On page 2 of the Office Action, claims 1-4, 6-7, 9-10, 14-15, 23, and 26 are rejected under 35 U.S.C. §102 (b) as being anticipated by Goldstein, et al. (U.S. Patent No. 5,899,937). Applicants respectfully traverse the rejections.

Goldstein, et al. pertains to a pulsatile flow system/bioreactor for developing recellularized heart valves (col. 1, lines 43-47). Goldstein's system is numerically simulated with a geometry shown in Fig. 2 (col. 7, lines 17 and 32). Goldstein sets forth a simulation of flow through a stented valve (col. 7, lines 25, 38) using computational fluid dynamic analysis. There is no physical device in Fig. 2 of Goldstein, and there is no tapered nozzle. Rather, "to simulate a stented valve, the flow field tapers as a nozzle over the next 1.15 cm to a typical stented valve outlet diameter of 21 mm." (col. 7, lines 38-40). Thus, a valve cannot be installed in the nozzle such that the nozzle would limit the opening of the valve to less than fully open.

The Goldstein specification only teaches that the leaflets are fully open. For example, it is stated that the leaflets are in a full open position along the sides of the nozzle (col. 7, lines 38-43), and the description of Fig. 2 clearly states that the "leaflets are shown in the fully open position". (col. 5, lines 2-3). Further, the text in Fig. 2 clearly states "fully open leaflets".

In addition, Goldstein's numerical simulations are experimentally verified with a normal living valve, which would be expected to be fully open upon application of fluid pressure in the forward direction. (See column 9, lines 50-52; column 13, lines 38-40; column 15, lines 44-67.)

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Goldstein does not teach every element of claims 1 and 23, and therefore fails to anticipate claims 1 and 23.

If the leaflets are thought of as being comparable to the flexible membrane, clearly the disclosure of Goldstein, et al. that the leaflets are in a fully open position cannot anticipate the limitation that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23). The rejection must be withdrawn.

Dependent claims 2-4, 6-7, 9-10, 14-15 and 26, which are dependent from independent claims 1 and 23, were also rejected under 35 U.S.C. §102(b) as being unpatentable over Goldstein, et al. While Applicants do not acquiesce with the particular

rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 23. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-4, 6-7, 9-10, 14-15 and 26 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-4, 6-7, 9-10, 14-15, 23, and 26 under 35 U.S.C. §102 (a) as being anticipated by Goldstein, et al.

2. Rejections under 35 USC § 103

On page 3 of the Office Action, claims 5, 11-13, 19-21, and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldstein, et al. in view of Pietsch, et al. (U.S. Patent No. 4,778,461).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations.

The disclosure of Goldstein, et al. is discussed above. The Examiner asserts that Pietsch et al. discloses a heart valve stent with commissure posts and having a membrane of polyurethane or silicon integrally cast with the stent. However, this disclosure does not teach leaflets less than fully open, so Pietsch et al. does not remedy

the deficiency in Goldstein et al. The combination of Goldstein, et al. and Pietsch, et al. still only discloses leaflets that are in a fully open position. Since Goldstein, et al. in view of Pietsch, et al. contains absolutely no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious. The rejection must be withdrawn.

Dependent claims 5, 11-13, 19-21 and 25, which are dependent from independent claims 1 and 23, were rejected under 35 U.S.C. §103(a) as being obvious over Goldstein et al in view of Pietsch et al. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 23. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 5, 11-13, 19-21 and 25 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 5, 11-13, 19-21, and 25 under 35 U.S.C. § 103(a) as being anticipated by Goldstein, et al. in view of Pietsch, et al

On page 3 of the Office Action, claims 8 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldstein, et al. in view of Eberhardt (U.S. Patent No. 5,176,153).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations.

The Examiner asserts that Eberhardt discloses the use of certain test frequencies. However, this disclosure does not teach leaflets less than fully open, so Eberhardt. does not remedy the deficiency in Goldstein. The combination of Goldstein, et al. and Eberhardt. still only discloses leaflets that are in a fully open position. Since Goldstein, et al. in view of Eberhardt contains absolutely no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious. The rejection must be withdrawn.

Dependent claims 8 and 24, which are dependent from independent claims 1 and 23, were rejected under 35 U.S.C. §103(a) as being obvious over Goldstein et al in view of Eberhardt. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 23. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional

features which further distinguish these claims from the cited references. Therefore, dependent claims 8 and 24 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 8 and 24 under 35 U.S.C. § 103(a) as being anticipated by Goldstein, et al. in view of Eberhardt.

3. Supplemental Comments

The Examiner stated that applicants define "does not fully open" as "opens no more than about 80% of the full open lumen at the inflow edge of the stent". This is not correct. While this is a limitation in some of the claims (claims 15, 26 and 29), it is not a limitation in claim 1 or any of the other claims.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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